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ENCLOSED ARE COPIES OF THE LATEST OFFICE ACTION--AN EXAMINER'S ANSWER--REMAILED DUE TO AN INCORRECT POSTAL ADDRESS.

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**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Paper No. 20

Application Number: 09/508,913
Filing Date: March 16, 2000
Appellant(s): UDEM ET AL.

Alan M. Gorden
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed July 23, 2003.

*(1) Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

*(2) Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

*(3) Status of Claims*

The statement of the status of the claims contained in the brief is correct.

*(4) Status of Amendments After Final*

No amendment after final has been filed.

*(5) Summary of Invention*

The summary of invention contained in the brief is correct.

*(6) Issues*

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows: It is noted that only claim 1 was mentioned in the 35 U.S.C. 112, first paragraph rejection, and claim 3 was inadvertently omitted from the prior 35 U.S.C. 112, first paragraph rejection. A telephone call was made to applicant (see interview summary Paper No. 19) and applicant was given the choice whether to receive a new action or to have claim 3 incorporated into the 35 U.S.C. 112, first paragraph rejection. In the interests of compact prosecution applicant elected to deal with the issue of claim 3 in the response to examiners answer. The appellant's statement of the issues in the brief is otherwise correct.

*(7) Grouping of Claims*

Appellant's brief includes a statement that claims 1 and 3 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

*(8) Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

*(10) Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1 and 3 are rejected under 35 U.S.C. 112, first paragraph. This rejection is set forth in prior Office Actions, Paper Nos. 11 and 15.

The specification, while being enabling for attenuated viral mutants that have multiple mutations (see table 21 and 22), does not reasonably provide enablement for of achieving an attenuated RSV virus by making a single mutation in the RNA polymerase gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The claims recite the generation of an attenuated RSV and the specification provides the sequence examples disclosed on tables 21 and 22. It is important to note that the mutations disclosed in table 21 and 22 were not recombinantly generated, they were sequenced from previously isolated viruses that were chemically modified and plaque purified.

The determination that "undue experimentation" would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the factual considerations. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. There are many factors to be considered when determining whether there is sufficient

evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The claims are drawn to a recombinant respiratory syncytial virus (RSV) subgroup B comprising an attenuating mutation having "at least one" mutation at position 353, 451, 1229, 2029 or 2050 and a vaccine composition.

The nature of the invention, currently, there is no known RSV vaccines comprising an attenuating virus with only one (at least one) attenuating mutation. There is also no suggestion in the art that demonstrates that a single mutation is sufficient to confer immunity. The specification does not provide any indication that a single amino acid change will result in the desired *ts (temperature sensitive)* phenotype. The 2B33F strain has mutation at locations 353, 451, 1229 and 2029 which results in the *ts* phenotype, a phenotypic reversion at a single location in a region that contains 3 other mutations does not provide evidence that a single mutation at 451 will result in a *ts* phenotype. The 2B20L strain has mutation at locations 154, 1616, 2029 and, 2050 which results in the *ts* phenotype, a phenotypic reversion at a single location in the region that contains 3 other mutations does not provide evidence that a single mutation will result in a *ts* phenotype. The context of the mutations observed between the stain 2B20L and 2B33F is very different, hence of ordinary skill cannot predict that the other mutations are not

involved in the expression of the *ts* phenotype. Therefore, the instant invention is not enabled for the full scope of the invention of a recombinantly generated RSV subgroup B having a single (at least one) mutation in the RNA polymerase gene

The state of the prior art, all known attenuated RSV vaccines have a number of mutations in additional sites throughout the entire genome. The prior art implies that a single amino acid change in the RSV L protein of the subgroup A will result in the desired *ts* phenotype (Juhasz et al. Journal of Virology 1997), however, upon close review it is apparent that there are multiple mutations from the wild type virus that actually lead to the desired phenotype (Juhasz et al., see table 1). Specifically, in the prior art the RSV subgroup A mutant (*cpts*530) has 6 mutations when compared to the wild type RSV A2wt virus and it is important to note that these mutations are not limited to the L protein alone. The incompletely attenuated phenotype *cp*RSV also has 6 mutations but is not as temperature sensitive as the *cpts*530 mutant. The relationship between the sequence of a protein and its tertiary structure (i.e. its activity) are not well understood and are not predictable (e.g. see Ngo et al., (V), in The Protein Folding Problem and Tertiary Structure Prediction,1994, Merz et al., (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495.). Because of this lack of predictability, extended experimentation would be required to determine which substitution or combination of substitution inside and possibly outside of the gene encoding the RNA polymerase protein is required to achieve the attenuated phenotype desired.

The level of one of ordinary skill, although it is well within the skill of those in the art to create a recombinant RSV comprising the instant mutation(s) recited, a priori predicting whether the mutation would have an attenuating effect on the pathogenicity of a virus is beyond the skill of those in the vaccine art.

The predictability in the vaccine art is very low. An effective, attenuating mutation within a virus must result in reduced pathogenicity, while retaining immunogenic effects to prime a host's immune system against a wild-type pathogen. The only way to determine if a mutation within a virus is adequately attenuated is to administer the virus to a host animal. The prior art does not disclose any attenuated RSV preventive agents with a single mutation. The skilled artisan would be unable to predict, in the absence of proof to the contrary, that the recombinant RSV instantly claimed is efficacious in preventing respiratory syncytial virus disease. The claim recitations that the instant mutation(s) are attenuating necessarily require evidence to support applicant's assertion that the claimed mutation(s) are attenuating.

The specification does not teach any pattern of mutations that is characteristic of attenuation. The specification teaches sequence comparisons of wt RSV strain 2B and attenuated RSV strain 2B33F and 2B20L. The divergent sequences identified between the two strains do not reveal conserved mutations among all of the known and characterized attenuated strains and wild type strains. The specification fails to demonstrate that one mutation, results in a *ts* phenotype. Each attenuated strain has multiple mutations, so it is not clear which mutations are responsible for attenuation. There is no working example provided by the inventor demonstrating that the claimed attenuated RSV comprising the minimum number of mutations (one) from wild type results in the *ts* phenotype. A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

Due to the breadth of the claims encompassing a recombinant RSV subgroup B comprising one attenuating mutation (at least one), the nature of the invention, drawn to preventing RSV disease with a recombinant virus comprising only one mutations, the state of the art, indicating that an attenuated virus comprises multiple mutations throughout the genome, the inability of the skilled artisan to a priori predict whether a mutation has an attenuating effect, the unpredictable state of the vaccine art, the lack of direction provided by the inventor, and the lack of working examples demonstrating an effective attenuation with a single mutation from wild type RSV as a vaccine, it is determined that an undue quantity of experimentation would be required for one skilled in the art to use the invention in its full scope.

Additionally, there are many different viral strains that belong to the RSV subgroup B, it is not clear that the mutations contemplated would possibly give rise the desired *ts* phenotype from other wild type viral isolates RSV (Venter et al. Journal of General Virology, 2001). Therefore, the instant invention is not enabled for the full scope of the invention.

***Claim Rejections - 35 USC § 102***

Claims 1 and 3 are rejected under 35 U.S.C. 102(e) as being anticipated by Randolph et al. (U.S. Pat. No. 5,932,222). This rejection is set forth in prior Office Actions, Paper Nos. 11 and 15.

The instant invention is drawn to an isolated, attenuated human RSV subgroup B virus which has "at least one" attenuating mutation in the RNA polymerase gene. For this office action, the preamble reciting "recombinantly-generated" is interpreted as a product-by-process, therefore, claims 1 and 3 were interpreted as "an isolated attenuated RSV virus" (which is a

*product*). Product-by-process claims are not limited to the manipulations of the recited steps, only to the structure implied by the steps, see M.P.E.P. Section 2113.

Randolph et al. disclose the mutation, characterization and isolation of various *ts* attenuations of RSV subgroup B virus. These attenuated viruses have been deposited with ATCC under the following accession numbers #VR2364 (=2R33F) and #VR2365 (=2B20L). The reference discloses using these attenuated viruses as a vaccine formulation (see claims 7-10). The mere recitation of the actual nucleotide sequences (see instant specification tables 21-22) that are inherently possessed by the attenuated viruses in the prior art, does not cause the claim drawn to those things to distinguish over the prior art (See *In re Best, Bolton, and Shaw* 195 USPQ 430 (CCPA 1977), *In re Schreiber* 44 USPQ2d 1429).

Applicant's arguments filed June 5, 2002 have been fully considered but they are not persuasive. Applicant argues that each and every element must be disclosed in the prior art to anticipate a claim. Additionally applicant argues that the prior art has not disclosed the structural characteristic, it has only disclosed the physical characteristics. Applicant's cite *ENZO Biochem Inc. v Gene Probe*, 62 USPQ2d 1289 (Fed. Cir. April 2, 2002) indicating that a deposit of a biological material does not suffice as sufficient written description regarding the disclosed the structural elements ie. the DNA sequence. This decision however was overturned in *ENZO Biochem Inc. v Gene Probe*, (Fed. Cir. 01-1230, July 15, 2002), specifically on the point that reference in a patent specification to a deposit of genetic material may suffice to describe that material (see conclusion). Therefore, the rejection is maintained.

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Randolph et al. (EP 0 567 100 A1). This rejection is set forth in prior Office Actions, Paper Nos. 11 and 15.

The instant invention is drawn to an isolated, attenuated human RSV subgroup B virus which has at least one attenuating mutation in the RNA polymerase gene. For this office action, the preamble reciting "recombinantly-generated" is interpreted as a product by process, therefore, claims 1-4 were interpreted as "an isolated attenuated RSV virus" (which is a *product*). Product-by-process claims are not limited to the manipulations of the recited steps, only to the structure implied by the steps, see M.P.E.P. Section 2113.

Randolph et al. disclose the mutation, characterization and isolation of various *ts* attenuations of RSV subgroup B virus, these isolates are designated as 2Bp33F (=2R33F) and 2Bp20L (=2B20L). The reference discloses using these attenuated viruses as a vaccine formulation (see claims 5-6, and tables 14, 16, 17, 18). The mere recitation of the actual nucleotide sequences (see instant specification tables 21-22) that are inherently possessed by the attenuated viruses in the prior art, does not cause the claim drawn to those things to distinguish over the prior art (See *In re Best, Bolton, and Shaw* 195 USPQ 430 (CCPA 1977), *In re Schreiber* 44 USPQ2d 1429).

Applicant's arguments filed June 5, 2002 have been fully considered but they are not persuasive. Applicant argues that each and every element must be disclosed in the prior art to anticipate a claim. Additionally applicant argues that the prior art has not disclosed the structural characteristic, it has only disclosed the physical characteristics. Applicant's cite *ENZO Biochem Inc. v Gene Probe*, 62 USPQ2d 1289 (Fed. Cir. April 2, 2002) indicating that a deposit of a biological material does not suffice as sufficient written description regarding the disclosed the

structural elements ie. the DNA sequence. This decision however was overturned in *ENZO Biochem Inc. v Gene Probe*, (Fed. Cir. July 15, 2002), specifically on the point that reference in a patent specification to a deposit of genetic material may suffice to describe that material (see conclusion). Therefore, the rejection is maintained.

***Double Patenting***

Claim 1 and 3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7-10 of U.S. Patent No. 5,932,222. This rejection is set forth in prior Office Actions, Paper Nos. 11 and 15.

Although the conflicting claims are not identical, they are not patentably distinct from each other because The instant invention is drawn to an isolated, attenuated human RSV subgroup B virus which has at least one attenuating mutation in the RNA polymerase gene. For this office action, the preamble reciting "recombinantly-generated" is interpreted as a product-by-process, therefore, claims 1-4 were interpreted as "an isolated attenuated RSV virus" (which is a *product*). Product-by-process claims are not limited to the manipulations of the recited steps, only to the structure implied by the steps (see above). Randolph et al. disclose the mutation, characterization and isolation of various *ts* attenuations of RSV subgroup B virus. These attenuated viruses have been deposited with ATCC under the following accession numbers #VR2364 (=2R33F) and #VR2365 (=2B20L). The reference discloses using these attenuated viruses as a vaccine formulation (see claims 7-10). The mere recitation of the actual nucleotide sequences (see instant specification tables 21-22) that are inherently possessed by the attenuated

viruses in the prior art, does not cause the claim drawn to those things to distinguish over the prior patent.

Applicant's arguments filed June 5, 2002 have been fully considered but they are not persuasive. Applicant argues that each and every element must be disclosed in the prior art to anticipate a claim. Additionally applicant argues that the prior art has not disclosed the structural characteristic, it has only disclosed the physical characteristics. Applicant's cite *ENZO Biochem Inc. v Gene Probe*, 62 USPQ2d 1289 (Fed. Cir. April 2, 2002) indicating that a deposit of a biological material does not suffice as sufficient written description regarding the disclosed the structural elements ie. the DNA sequence. This decision however was overturned in *ENZO Biochem Inc. v Gene Probe*, (Fed. Cir. July 15, 2002), specifically on the point that reference in a patent specification to a deposit of genetic material may suffice to describe that material (see conclusion). Therefore, the rejection is maintained.

***(11) Response to Argument***

In response to the lack of enablement for the full scope of attenuating mutations claimed, appellant submits that the skilled artisan would be able to follow the teachings in the specification to ascertain whether specific mutations confer sufficient attenuation. Appellant points to specific recitations in the disclosure detailing the specific mutations claimed, how the skilled artisan would rescue a virus comprising specific mutations, confirm that the rescued virus contains the desired phenotype and conduct challenge experiments in the appropriate animal model.

In response to the examiner's assertion that one skilled in the art cannot a priori predict mutations that are *ts* phenotype attenuating, appellant asserts that the proper test is not a priori prediction, but whether the skilled artisan would be able to ascertain whether a virus comprising one or more of the claimed mutations is sufficiently attenuated. Appellant argues that the specification enables the skilled person to utilize the mutations identified to construct and test the recombinant strains for attenuation and practice invention without undue experimentation.

Appellant's arguments have been fully considered, but are found to be unpersuasive. The disclosure does not teach a virus comprising a single mutation at position locations 353, 451, 1229 and 2029, that possesses the functional characteristic required by the claims. The disclosure does not provide guidance or a working example demonstrating that incorporation of the recited mutation in the wild type genome will result in the required attenuating *ts* phenotype. Appellant is claiming that the instant mutations are attenuating and invite the skilled artisan to perform further experiments to confirm the assertions stated in the claims.

While the presence of a working example is not required in an application, it is maintained that there must be some teaching, evidence or demonstration provided in the disclosure that the invention is enabled in its full scope without undue experimentation by the skilled artisan. The disclosure does not provide evidence demonstrating that the minimum number of mutations (at least one) claimed results in the required attenuating phenotype. Each attenuated strain known in the art has multiple mutations, so it is not clear which mutations are responsible for the attenuating phenotype. There is no teaching in the art demonstrating that mutations in only the polymerase region is sufficient to confer attenuation.

Therefore, due to the nature of the invention of a vaccine for RSV comprising "at least one" specific mutation, the lack of evidence in the specification that these mutations have the required "attenuating" characteristic on the virus phenotype, the lack of working examples incorporating an RSV with the minimum number of mutations claimed in a vaccine composition, the unpredictable nature of the vaccine art, the state of the art indicating that attenuated RSV vaccines have a number mutations throughout the genome and the lack of predictability for which specific mutations are responsible for attenuation, it is determined that an undue quantity of experimentation would be required to practice the invention in its full scope. For these reasons, it is concluded that the application does not balance the factors set forth in *Wands*.

In response to the 35 U.S.C. 102(e) rejection as being anticipated by Randolph et al. (U.S. Pat. No. 5,932,222). The arguments are as follows:

1) does not make the sequences publicly accessible or contain an enabling disclosure (applicants cite prior case rejection).

2) did not provide the descriptive matter of the sequences.

3) did not provide clear and convincing evidence of inherent anticipation.

4) did not describe appellant's invention sufficiently to have placed a person skilled in the art in possession of it.

5) appellant argues that the cited prior art did not deposit the wild type 2B stain and therefore comparison between the sequences are not possible based on the prior art.

Appellant's arguments have been fully considered, but are found to be unpersuasive. Rudolph specifically teaches that the strain 2B33F is attenuated in column 4, lines 45-47.

Contrary to appellant's assertion in 1) and 4), Rudolph does make the sequences publicly available by depositing strain 2B33F and strain 2B20L in a recognized depository and satisfies the provisions of the Budapest Treaty. Strain 2B33F is designated by ATCC accession number VR 2364, see column 8, line 59, which is recited in claim 13. Strain 2B20L is designated by ATCC accession number VR 2368, see column 8, line 59, which is recited in claim 10. Rudolph, having satisfied the deposit criteria by the Office, ensures that: (a) access to the invention will be afforded to one determined by the Commissioner to be entitled thereto; (b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of the patent; (c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material; (d) a viability statement in accordance with the provisions of 37 CFR 1.807; and (e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification. The deposited strain 2B33F and 2B20L by Rudolph is required to maintain all of the characteristics necessary to practice the invention patented by Rudolph. These characteristics include the functional *ts* phenotype of attenuation, as well as the structural sequences required to maintain the functional phenotype. Therefore, Rudolph and the public have possession of strain 2B33F and 2B20L, which includes all of its phenotypic, genotypic, functional and structural characteristics.

In response to appellant's assertion in 2), the description of the sequences in the deposited strain are an inherent characteristic of the deposited strain. Appellant has not offered any convincing evidence that contradicts *In re Spada*, that the recitation of a newly discovered

characteristic of an old product does not render the product patentable. Rudolph and the public have possession of the product and all of the characteristics inherent in that product. The discovery of a previously unappreciated characteristic of a prior art composition does not render an old product newly patentable. Inherent characteristics disclosed within a prior art reference are not required to be appreciated or recognized for the reference to be anticipatory. *Atlas Power Co. v. IRECO Inc.*, 190 F.3d 1342, 51 USPQ2d 1943 (Fed. Cir. 1999). Further, [u]nder the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates." *Mehl/Biophile Int'l Corp. v. Milgram*, 192 F.3d 1362, 1365 (Fed. Cir. 1999). The deposited strain of Rudolph inherently possesses the structur and explicit functional features necessary to maintain the deposit agreement and enable vaccination with the attenuated strain. *ENZO Biochem Inc. v Gene Probe*, (Fed. Cir. July 15, 2002) indicates that reference in a patent specification to a deposit of genetic material may suffice to describe that material (see conclusion).

In response to 3), Rudolph is not required to characterize inherent properties of the patented strain. Appellant's disclosure provided the clear and convincing evidence of inherent anticipation of 2B33F and 2B20L see Tables 21 and 22 of the instant disclosure.

In response to 5) applicants argument that the wild type 2B strain was not deposited in U.S. Pat. No. 5,932,222 and therefore the key attenuating loci cannot be compared is not convincing. The claim is not drawn to a comparison of the isolated, attenuated human respiratory syncytial virus with the wild type virus, the wild type virus sequence referred to in the claim (SEQ ID NO:2) serves to allow for the alignment of the residues. As the deposited

strains have originated from the wild type virus the numbering of the amino acid sequence would be conserved, indicating that 2B33F and 2B20L have the mutants at the indicated loci.

The instant claims are drawn to an isolated, recombinantly-generated attenuated RSV subgroup B having specific at least one attenuating mutations at 353, 451, 1229, 2029 or 2050. For these reasons, it is maintained that Rudolph anticipates the invention.

In response to the 35 U.S.C. 102(b) rejection as being anticipated by Randolph et al. (EP 0 567 100 A1). The arguments are as follows:

1) does not make the sequences publicly accessible or contain an enabling disclosure (applicants cite prior case rejection).

2) did not provide the descriptive matter of the sequences.

3) did not provide clear and convincing evidence of inherent anticipation.

4) did not describe appellant's invention sufficiently to have placed a person skilled in the art in possession of it.

5) appellant argues that the cited prior art did not deposit the wild type 2B stain and therefore comparison between the sequences are not possible based on the prior art.

Appellant's arguments have been fully considered, but are found to be unpersuasive. Rudolph specifically teaches that the strain 2B33F and 2B20L is attenuated see page 18, lines 2-14. Contrary to appellant's assertion in 1) and 4), Rudolph does make the sequences publicly available by depositing strain 2B33F and strain 2B20L in a recognized depository and satisfies the provisions of the Budapest Treaty. Strain 2B33F is designated by ATCC accession number VR 2364 and strain 2B20L is designated by ATCC accession number VR 2368, see page 6, line

54-58. Rudolph, having satisfied the deposit criteria of the Budapest Treaty, ensures that: (a) access to the invention will be afforded to one determined by the Commissioner to be entitled thereto; (b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of the patent; (c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material; (d) a viability statement in accordance with the provisions of 37 CFR 1.807; and (e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification. The deposed strain 2B33F and 2B20L by Rudolph is required to maintain all of the characteristics necessary to practice the invention patented by Rudolph. These characteristics include the functional *ts* phenotype of attenuation, as well as the structural sequences required to maintain the functional phenotype. Therefore, Rudolph and the public have possession of strain 2B33F and 2B20L, which includes all of its phenotypic, genotypic, functional and structural characteristics.

In response to appellant's assertion in 2), the description of the sequences in the deposited strain are an inherent characteristic of the deposited strain. Appellant has not offered any convincing evidence that contradicts *In re Spada*, that the recitation of a newly discovered characteristic of an old product does not render the product patentable. Rudolph and the public have possession of the product and all of the characteristics inherent in that product. The discovery of a previously unappreciated characteristic of a prior art composition does not render an old product newly patentable. Inherent characteristics disclosed within a prior art reference are not required to be appreciated or recognized for the reference to be anticipatory. *Atlas Power*

*Co. v. IRECO Inc.*, 190 F.3d 1342, 51 USPQ2d 1943 (Fed. Cir. 1999). Further, [u]nder the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates." *Mehl/Biophile Int'l Corp. v. Milgram*, 192 F.3d 1362, 1365 (Fed. Cir. 1999). The deposited strain of Rudolph inherently possesses the structure and explicit functional features necessary to maintain the deposit agreement and enable vaccination with the attenuated strain. *ENZO Biochem Inc. v Gene Probe*, (Fed. Cir. July 15, 2002) indicates that reference in a patent specification to a deposit of genetic material may suffice to describe that material (see conclusion).

In response to 3), Rudolph is not required to characterize inherent properties of the patented strain. Appellant's disclosure provided the clear and convincing evidence of inherent anticipation of 2B33F and 2B20L see Tables 21 and 22 of the instant disclosure.

In response to 5) applicants argument that the wild type 2B strain was not deposited in EP 0 567 100 A1 and therefore the key attenuating loci cannot be compared is not convincing. The claim is not drawn to a comparison of the isolated, attenuated human respiratory syncytial virus with the wild type virus, the wild type virus sequence referred to in the claim (SEQ ID NO:2) serves to allow for the alignment of the residues. As the deposited strains have originated from the wild type virus the numbering of the amino acid sequence would be conserved, indicating that 2B33F and 2B20L have the mutants at the indicated loci.

The instant claims are drawn to an isolated, recombinantly-generated attenuated RSV subgroup B having specific at least one attenuating mutations at 353, 451, 1229, 2029 or 2050. For these reasons, it is maintained that Rudolph anticipates the invention.

In response to applicants arguments regarding the double patenting rejection, Appellant's brief presents arguments relating to "whether the Final Rejection was proper on Second Action" it is pointed out the Double Patenting rejection was made in the rejection is set forth in prior Office Actions, Paper Nos. 11 and 15. Furthermore, this issue relates to petitionable subject matter under 37 CFR 1.181 and not to appealable subject matter. See MPEP § 1002 and § 1201. Applicants arguments are essentially the same as those made in the 35 U.S.C. 102(e) and 102(b) rejection above. Applicant further argues that *In Re Sporman and Heike* 150 USPQ 449 which indicates that inherency and obviousness are entirely different question. In this instance applicant is arguing the obviousness type double patenting rejection, which is based entirely on a single reference rejection. The choice of obvious type double patenting over the statutory type double patenting is based on the claim language, which is not identical. However, in this instance the scope of the claim is identical in the respect to the deposited 2B33F and 2B20L and their description. *ENZO Biochem Inc. v Gene Probe*, (Fed. Cir. July 15, 2002) indicates that reference in a patent specification to a deposit of genetic material may suffice to describe that material (see conclusion). Therefore, the double patenting rejection is maintained.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

ULRIKE WINKLER, PHD.
PATENT EXAMINER

Ulrike Winkler
September 5, 2003

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